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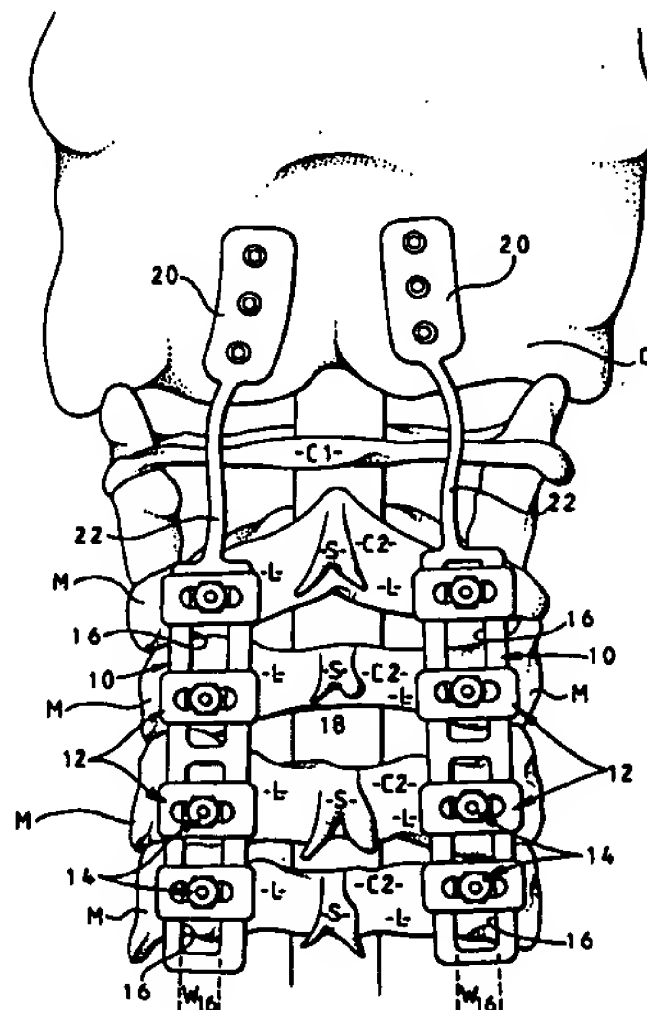
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(54) Title: CERVICAL FIXATION SYSTEM

(57) Abstract

A cervical fixation system comprises pair of elongate fixation plates (10) having longitudinally extending slots (16) therethrough and being adapted to engage, in use, against the lateral masses M on respective sides of the spinal processes S of cervical vertebrae C to be fixed in use. Bridges (12) are respectively engaged with the plates (10) so as to bridge the slot (16) in the plate laterally. Each bridge (12) has a slot (24) therethrough which extends longitudinally of the bridge (12). A plurality of fixation screws (14) each have (a) a shank (32) engaged in a lateral mass M of one of the cervical vertebrae C, (b) an abutment boss (34) disposed between and engaging the cervical vertebra and one of the bridges (12) and which is oversized relative to the width w_{24} of the slot (24) through such bridge, (c) a post (36) extending from the abutment boss (34) and being of a size to pass through such slot (24), and (d) a head (38) which is oversized relative to the width w_{24} of such slot (24) and which is securable to the post (36) so that the bridge (12) can be trapped between the head (38) and the abutment boss (34) of the screw (14) after the shank (32) of the latter has been secured to the vertebra C.



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CERVICAL FIXATION SYSTEM

This invention relates to a cervical fixation system for enabling two or more cervical vertebrae to be fixed or fused together and, in some cases, to the occiput in a patient.

It is known to fix together two or more cervical vertebrae using a pair of elongate slotted plates which are positioned by the surgeon so as to engage the respective lateral masses on either side of the spinous processes of these vertebrae. Bone screws are then passed through the slots in the plates and screwed into the cervical bone (usually either the lateral masses or the pedicles). However, there are several problems with this type of system:-

- (a) the screws may work loose because of instability and relative motion between the vertebrae,
- (b) the slots and underlying vertebrae do not always coincide in position and therefore some segments to be fused may be missed because of inability to insert a screw,
- (c) the plate obscures the operating surgeon's view of the underlying bone, which can result in incorrect screw placement,
- (d) the bone is relatively thin, there is therefore no margin of error for incorrect screw placement (once a screw is inserted wrongly, it is difficult to re-insert it because of insufficient bone purchase),
- (e) if it is impossible to insert a screw into a particular segment (for technical reasons), there is no alternative method of fixating that segment to the plate, and
- (f) there is no method of cross-linking plates on each side of the vertebral spinous process.

It is an object of a first aspect of the present invention to provide a cervical fixation system in which at least some of the above problems can be obviated or mitigated.

According to said first aspect of the present invention, there is provided a cervical fixation system comprising a pair of elongate fixation plates having longitudinally extending slots therethrough and being adapted to engage, in use, against the lateral masses on respective sides of the spinal processes of cervical vertebrae to be fixed in use; a plurality of bridges of which each is adapted to be engaged with a respective one of the plates so as to bridge the slot in the plate laterally, each bridge having a slot therethrough which extends longitudinally of the bridge; and a plurality of fixation screws each having (a) a shank for engagement in one of the cervical vertebrae (preferably a lateral mass of the latter), (b) an abutment means which is adapted to be disposed between and engage the cervical vertebra and one of the bridges and which is oversized relative to the width of the slot through such bridge, (c) a post extending from the abutment means and being of a size to pass through such slot, and (d) a head which is oversized relative to the width of such slot and which is securable to the post so that the bridge can be trapped between the head and the abutment means of the screw after the shank of the latter has been secured to the vertebra.

Thus, with the fixation system of the first aspect of the present invention, the fixation screws can be firmly secured in the optimum positions in the cervical vertebrae, and then the plates and the bridges can be secured in position using the heads of the screws. The heads of the screws secure the plates in position via the bridges by engagement with the screws whose shanks have already been anchored into the vertebrae. With such

an arrangement, there is a considerably reduced risk of the screws working loose in practice. The fact that the bridges can be positioned anywhere along the plates and that the bridges and the plates have mutually transverse slots therein means that it is possible to accommodate for fixation screws which have been secured in the ideal positions having regard to the anatomy and bone condition of the patient.

The abutment means on the fixation screws preferably have an effective depth (ie the dimension extending in the longitudinal axis of the screw) which is substantially equal to the thickness of the fixation plates. In this respect, allowance is preferably made for setting of the screws in the vertebrae at an inclination (up to 60° laterally and up to 60° cranially) in order to engage the lateral masses thereof.

Preferably, the head of each fixation screw has a part-spherical undersurface for engagement in a respective one of a row of laterally interconnected part-spherical recesses located in the bridge such that the slot opens into the recesses. Preferably, three such recesses are provided.

Each bridge may have projections at each end thereof which are adapted to engage respective longitudinal side edges of the fixation plate to prevent lateral bowing of the plate in use.

Preferably also, mutually engaging formations on the bridges and the plates are provided so that the bridges can be snap-fitted onto the plates. For example, the ends of the bridges may have hooked ribs which can

be snap-fitted into undercut regions on respective longitudinal side edges of the fixation plates

The plates may be of any desired length so as to fix the required number of vertebrae. The system according to the present invention may include a plurality of pairs of plates of different sizes and/or lengths so that the surgeon can choose plates which are most appropriate for the patient. Alternatively, the plates may be of one length and cut to the appropriate size by the surgeon.

The plates may be designed to extend as far as one or more of the dorsal vertebrae. In which case, the screws for engagement with such vertebrae may be pedicle screws.

The plates may include a region designed to be fixed to the cranium (eg the occiput) of the patient. Such cranial region may be joined to the remainder of the plate by means of a deformable region which can be bent to facilitate correct fitting.

The screws may be cannulated so as to allow them to be screwed into the vertebrae over a previously inserted guide rod or wire.

The screw for C1/C2 fixation may also be a lag screw (partially threaded) to allow retraction of C1 on C2.

At least one of mutually engaging surfaces of the fixation plates and the bridges may have serrations, ribs or any other type of roughening to improve grip between these parts in use.

At least one of the bridges may be provided with at least one hook adapted to engage at least one of the vertebrae. This is particularly useful in situations where the condition of one of the vertebra makes it difficult or impossible to use a fixation screw. A hook or hooks may be provided for the thoracic vertebra(e), eg vertebrae T1 and/or T2. It is preferred for at least one of the hooks to be adjustable relative to the bridge and to be fixable in its adjusted position.

Such a hook arrangement may be used in a modified cervical fixation system without the above-mentioned plates and bridges of the system according to said first aspect of the present invention. The modified system may be used for fixation of the C₁-C₂ vertebrae.

A cervical fixation system is known in which the C1-C2 cervical vertebrae are secured using a pair of C-shaped hook elements. Each hook element comprises a pair of oppositely directed hooked arms which are engagable over the pedicles of the respective vertebrae and which are telescopically movable and crimpable to lock the arms together when in the required position to secure the vertebrae. A disadvantage of such a system is that it is not particularly secure.

It is an object of a second aspect of the present invention to obviate or mitigate the above disadvantage.

According to said second aspect of the present invention, there is provided a cervical fixation system comprising (i) a body having an apertured flange which is (a) adapted to be secured to a lateral mass of a cervical vertebra and (b) provided with a first hook portion extending laterally of said flange; (ii) a hooked element having a second hook

portion which is oppositely directed relative to the first hook portion, said hooked element extending laterally of said flange and being slidable towards and away from the first hook portion; and (iii) securing means for securing the hooked element against sliding movement relative to said flange and first hook portion.

The provision of the apertured flange enables the cervical fixation system to be secured in position by way of a three-point mounting consisting of the two hook portions which engage over the respective vertebrae, and a screw or other securing element which engages with the apertured flange and in the vertebra with which the first hook portion is engaged.

The apertured flange may have an elongate aperture or more than one aperture therethrough to enable flexibility in positioning of the flange relative to the securing element which is engaged therewith in use. There may be one or more curved or part-spherical recesses in the region of the aperture(s) in the flange so as to receive a curved or part-spherical region of a head of a securing screw. Such an arrangement permits the axis of the securing screw to be inclined non-perpendicularly relative to the flange whereby to enable the screw to be optimally positioned in the vertebra.

In one embodiment, the apertured flange has a laterally projecting connection portion (eg a rod) which carries the first hook portion and upon which the hooked element is slidably mounted.

The securing means may be defined by a crimpable or otherwise deformable region of the hooked element and/or the connection portion to enable these parts to be secured against relative sliding movement.

In another embodiment, the apertured flange has a clamping member hingedly secured thereto so that a rod extending from the hooked element can be clamped between the clamping member and the flange to secure the hooked element against sliding movement. Preferably, the clamping member is apertured so that the screw or the like can pass in use through both the clamping member and the apertured flange. An example of such a construction is disclosed in WO96/02199.

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:-

Fig. 1 is a view of one example of cervical fixation system according to said first aspect of the present invention shown fixed at both cervical and occipital regions,

Figs 2, 3 and 4 are an axial section, a cross-section and a perspective view, respectively, of a bridges forming part of the system of Fig. 1, Figs 5 and 6 are views showing the lateral and cranial inclination of a lateral mass-engaging fixation screw forming part of the system of Fig. 1, Fig. 7 is a view showing an alternative embodiment where a bridge is provided with a pair of cervical hooks,

Fig. 8 is a view showing a further alternative embodiment,

Fig. 9 is a perspective view of one example of a cervical fixation system according to said second aspect of the present invention.

Referring now to Fig. 1, the system comprises basically a pair of elongate biocompatible metal cervical fixation plates 10, bridges 12 and fixation screws 14. Each plate 10 is planar, has mutually parallel longitudinal side edges and has a pair of longitudinally extending slots 16 therethrough which are separated by a thin web 18. It is within the

scope of the present invention, however, to use a single slot or more than two slots. The slots 16 occupy as large an area of the plate 10 as possible consistent with ensuring sufficient strength of the latter. Each plate 10 has an upper extension defining an occipital region 20 and an intermediate deformable region 22 which passes over the C1 vertebra. In this embodiment, the plates 10 extend over cervical vertebrae C1 to C5, but other longer or shorter lengths may be used to enable more or less vertebrae to be fixed. The plates 10 respectively engage the laminae L and lateral masses M on opposite sides of the spinal processes S of the vertebrae C2 to C5.

Referring now also to Figs. 2 to 4, each bridge 12 is defined by a generally rectangular metal plate and has a slot 24 therethrough which extends longitudinally of the bridge 12. The length of the bridge 12 is marginally greater than the width of the plate 10. In its upper surface, the bridge has a row of three part-spherical, laterally interconnected recesses 26a, 26b and 26c therein into the bases of which the slot 24 opens. At its ends, the bridge 12 has a pair of mutually parallel ribs 28 extending away from a surface of the bridge 12 which is engaged with the plate 10 in use. The ribs 28 cooperate with the respective longitudinal side edges of the plate 10 (see particularly Fig. 5) to prevent the relatively thin side regions of the plates 10 from bowing outwardly in use.

Each fixation screw 14 has a screw-threaded shank 32 which is adapted to be engaged in the lateral mass M of a respective one of the vertebrae C2 to C7 or pedicles of thoracic vertebrae. The C2 screw may or may not be inserted through the articular joint into C1. If it does not engage C1, the C2 screw is inserted into the C2 pedicle. For this reason,

it extends into the vertebra with both a lateral inclination (Fig. 5) and a cranial inclination (Fig. 6). The screw 14 also has an abutment boss 34 at the top of the shank 32. The abutment boss 34 has an effective depth d_{34} which is about equal to the thickness t_{10} of the plate 10 taking into account the effect produced by inclination of the screw 14 (see Fig. 5). The effective width w_{34} of the abutment boss 34 is appreciably less than the w_{16} of the slot 16 in the plate 10, but greater than the width w_{24} (Fig. 4) of the slot 24 in the bridge 12. Thus, oversizing of the boss 34 relative to the width w_{24} of the slot 24 ensures that it will abut against the underside of the bridge 12 and prevent the latter from being deformed into the slot 16 in the plate 10.

The screw 14 further has a screw-threaded post 36 extending away from the abutment boss 34. The post has a diameter which is less than the width w_{24} of the slot 24 in the bridge 12 and a length such that it can project through the bridge 12 for engagement by an internally screw-threaded head 38 of the screw 14. The head 38 has a width w_{38} which is greater than the width w_{24} of the slot 24 and has a part-spherical undersurface 40 which engages with one of the part-spherical recesses 26a to 26c. In Fig. 1, all the heads 38 are shown as being engaged in the central recess 26b, but the actual recess 26 used depends upon the relative positions of the screws 14 to be engaged by each plate 10.

In use, the shanks 32 of the screws 14 are screwed into the lateral masses M of the respective vertebrae C2 to C7 until the abutment bosses 34 are engaged against the surface of the lateral mass M. This ensures that the screws 14 are firmly anchored in place. The plates 10 are then placed in the correct positions against the lateral masses M of the vertebrae so that the surgeon can check the amount by which the regions

22 must be bent to enable to occipital regions 20 to seat closely against the occiput O of the patient. After the regions 22 have been bent by the correct amounts, the plates 10 are then repositioned over the posts 36, and the bridges 12 located in position so that the posts 36 pass through the slots 24. The heads 38 are then screwed down onto the posts 36 so that they engage in appropriate ones of the recesses 26a to 26c in the bridges 12 whereby the latter are trapped between the heads 38 and the bosses 34, and the plates 10 are firmly clamped into place against the laminae L.

Finally, the occipital regions 20 are secured to the occiput O by means of screws 42.

In the embodiment of Fig. 7, similar parts to those described above are accorded the same reference numerals. In this case, the bridge 12 is provided with a lateral extension piece 44 which extends towards the spinal process and which is curved so as to define a hook 46 directed cranially. The extension piece 44 has a transverse hole therein in which a bar 48 carrying a caudally directed hook 50 is slidably mounted. This bridge 12 is designed to be used to fix a cervical vertebra, for example the C3 vertebra, which is in such poor condition that a screw cannot safely be used. The bridge 12 may also be used to further secure the C1/C2 complex. In this case, the bridge 12 is secured to the C2 vertebra using the screw 14 as described previously and also the hook 46 which engages the lamina L of the C2 vertebra. Then, the hook 50 is engaged with the lamina L of the C1 vertebra and locked in position by crimping the extension piece 44 around the hole so as to lock the bar 48 in position. In addition, for isolated C1/C2 fusion, a bridge may be used to secure hooks to C1/C2 and a C2/C1 screw without a plate.

In Fig. 7, the bridge 12 is shown with a plurality of positioning locations for the screw 14. However, this is not essential, and so the bridge 12 illustrated in Fig. 7 may be provided with only a single positioning location for the screw 14.

Referring now to Fig. 8, there is shown a further type of bridge 12 which is used to cross link the two parallel plates 10 located one on either side of the spinous processes. In this case, a cross bar 52 is provided with a bridge 12 at each end so that each bridge 12 can be secured to a respective one of the plates 10 using the previously described screws 14.

Referring now to Fig. 9, there is shown a cervical fixation system according to said second aspect of the present invention. Such system comprises a rectangular, biocompatible metal flange 100 having an aperture in the form of a slot 102 therethrough which extends longitudinally of the flange 100. In its upper surface, the flange 100 has a row of three part-spherical, laterally interconnected recesses 104a, 104b and 104c therein into the bases of which the slot 102 opens. At one of its ends, the flange 100 is provided with a laterally extending arm 106 carrying a first hook portion 108 at its flange-remote end. The first hook portion 108 extends approximately perpendicularly relative to the arm 106 and to the plane of the flange 100. A bore 110 extends through the arm 106 in the region of the junction of the latter with the first hook portion 108. The axis of the bore 110 is approximately perpendicular to the direction in which the hook portion 108 projects from the arm 106.

The cervical fixation system according to said second aspect of the present invention also includes a hooked element 112 comprising a

second hook portion 114 and a rod 116. The second hook portion 114 is mounted on one end of the rod 116. The rod 116 is slidably engaged in the bore 110 so that the second hook portion 114 faces the first hook portion 108 and the distance of separation of the hook portions 108 and 114 can be varied by sliding the rod 116 relative to the arm 106.

In use, a lag screw 14 of the type illustrated in Figs 6 and 7 is inserted into the appropriate lateral mass of the C2 vertebra. With the rod 116 of the hooked element 112 slidably engaged in the bore 110, the hook portions 108 and 114 are engaged over the laminae of the respective C2 and C1 vertebrae, with the post 36 of the screw 14 being engaged in the appropriate part of the slot 102 in the flange 100. Then the head 38 of the screw 14 is engaged with the post 36 and tightened down so as to secure the flange to the C2 vertebra. The rod 116 is then slid in the inferior direction to cause the hook portions 108 and 114 to be brought towards one another whereby to bear against the respective laminae with the desired force, and the part of the arm 106 traversed by the bore 110 is then deformed by a suitable crimping tool to crimp the arm 106 securely against the rod 116.

Thus, the C1 and C2 vertebrae are caused to be firmly secured together at three locations.

CLAIMS

1. A cervical fixation system comprising a pair of elongate fixation plates having longitudinally extending slots therethrough and being adapted to engage, in use, against the lateral masses on respective sides of the spinal processes of cervical vertebrae to be fixed in use; a plurality of bridges of which each is adapted to be engaged with a respective one of the plates so as to bridge the slot in the plate laterally, each bridge having a slot therethrough which extends longitudinally of the bridge; and a plurality of fixation screws each having (a) a shank for engagement in one of the cervical vertebrae (preferably a lateral mass of the latter), (b) an abutment means which is adapted to be disposed between and engage the cervical vertebra and one of the bridges and which is oversized relative to the width of the slot through such bridge, (c) a post extending from the abutment means and being of a size to pass through such slot, and (d) a head which is oversized relative to the width of such slot and which is securable to the post so that the bridge can be trapped between the head and the abutment means of the screw after the shank of the latter has been secured to the vertebra.
2. A system as claimed in claim 1, wherein the abutment means on the fixation screws have an effective depth which is substantially equal to the thickness of the fixation plates.
3. A system as claimed in claim 1 or 2, wherein the head of each fixation screw has a part-spherical undersurface for engagement in a respective one of a row of laterally interconnected part-spherical recesses located in the bridge such that the slot opens into the recesses.

4. A system as claimed in any preceding claim, wherein each bridge has projections at each end thereof which are adapted to engage respective longitudinal side edges of the fixation plate to prevent lateral bowing of the plate in use.
5. A system as claimed in any preceding claim, wherein mutually engaging formations on the bridges and the plates are provided so that the bridges can be snap-fitted onto the plates.
6. A system as claimed in any preceding claim, wherein the plates include a region designed to be fixed to the cranium of the patient.
7. A system as claimed in claim 6, wherein said region is joined to the remainder of the plate by means of a deformable region which can be bent to facilitate correct fitting.
8. A system as claimed in any preceding claim, wherein the screws are cannulated.
9. A system as claimed in any preceding claim, wherein at least one of the bridges is provided with at least one hook adapted to engage at least one of the vertebrae.
10. A system as claimed in claim 9, wherein at least one of the hooks is adjustable relative to the bridge and to be fixable in its adjusted position.
11. A system as claimed in any preceding claim, wherein at least one of mutually engaging surfaces of the fixation plates and the bridges

has serrations, ribs or any other type of roughening to improve grip between these parts in use.

12. A system as claimed in any preceding claim, wherein at least one of the bridges for one of the fixation plates is provided with a cross bar connected with one of the bridges for the other of the fixation plates.

13. A cervical fixation system comprising (i) a body having an apertured flange which is (a) adapted to be secured to a lateral mass of a cervical vertebra and (b) provided with a first hook portion extending laterally of said flange; (ii) a hooked element having a second hook portion which is oppositely directed relative to the first hook portion, said hooked element extending laterally of said flange and being slidable towards and away from the first hook portion; and (iii) securing means for securing the hooked element against sliding movement relative to said flange and first hook portion.

14. A system as claimed in claim 13, wherein the apertured flange has an elongate aperture or more than one aperture therethrough.

15. A system as claimed in claim 13 or 14, wherein one or more curved or part-spherical recesses are provided in the region of the aperture(s) in the flange so as to receive a curved or part-spherical region of a head of a securing screw or the like fixing member.

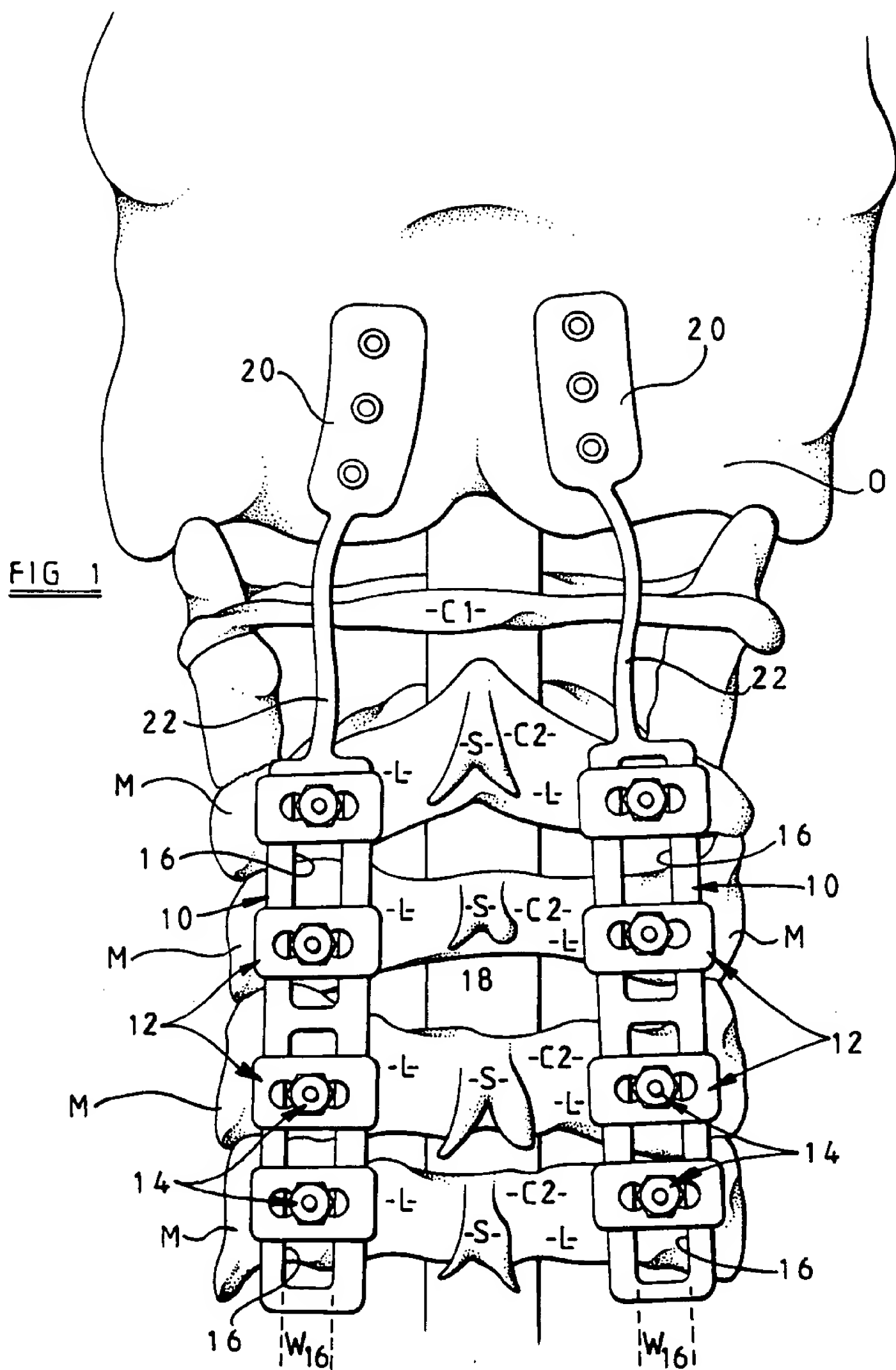
16. A system as claimed in claim 13, 14 or 15, wherein the apertured flange has a laterally projecting connection portion which carries the first hook portion and upon which the hooked element is slidably mounted.

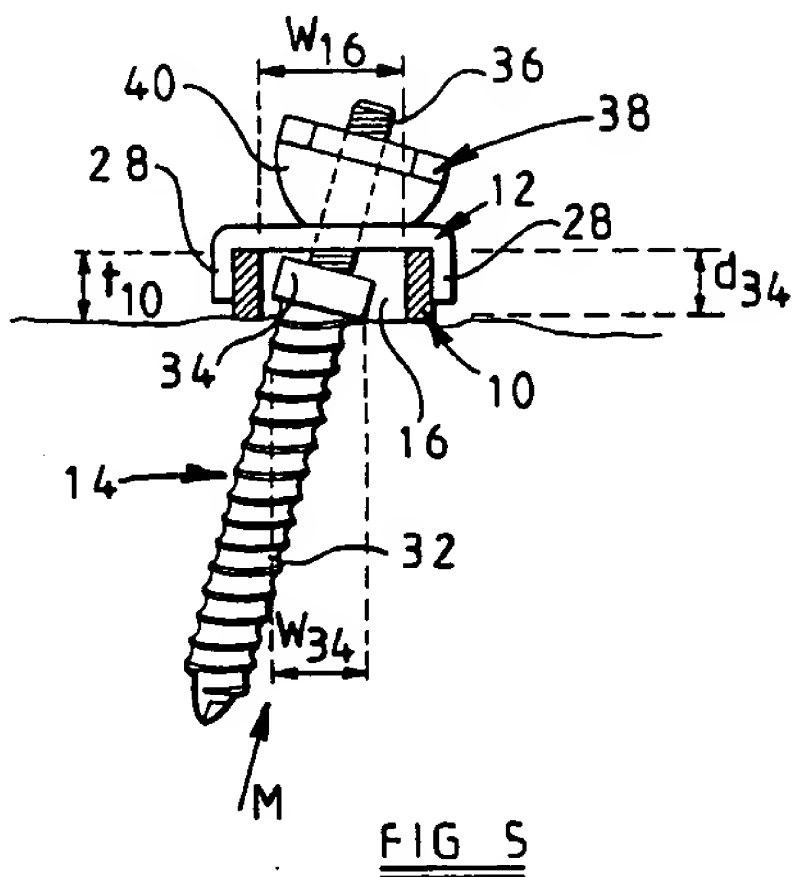
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17. A system as claimed in claim 16, wherein the securing means is defined by a crimpable or otherwise deformable region of the hooked element and/or the connection portion to enable these parts to be secured together against relative sliding movement.

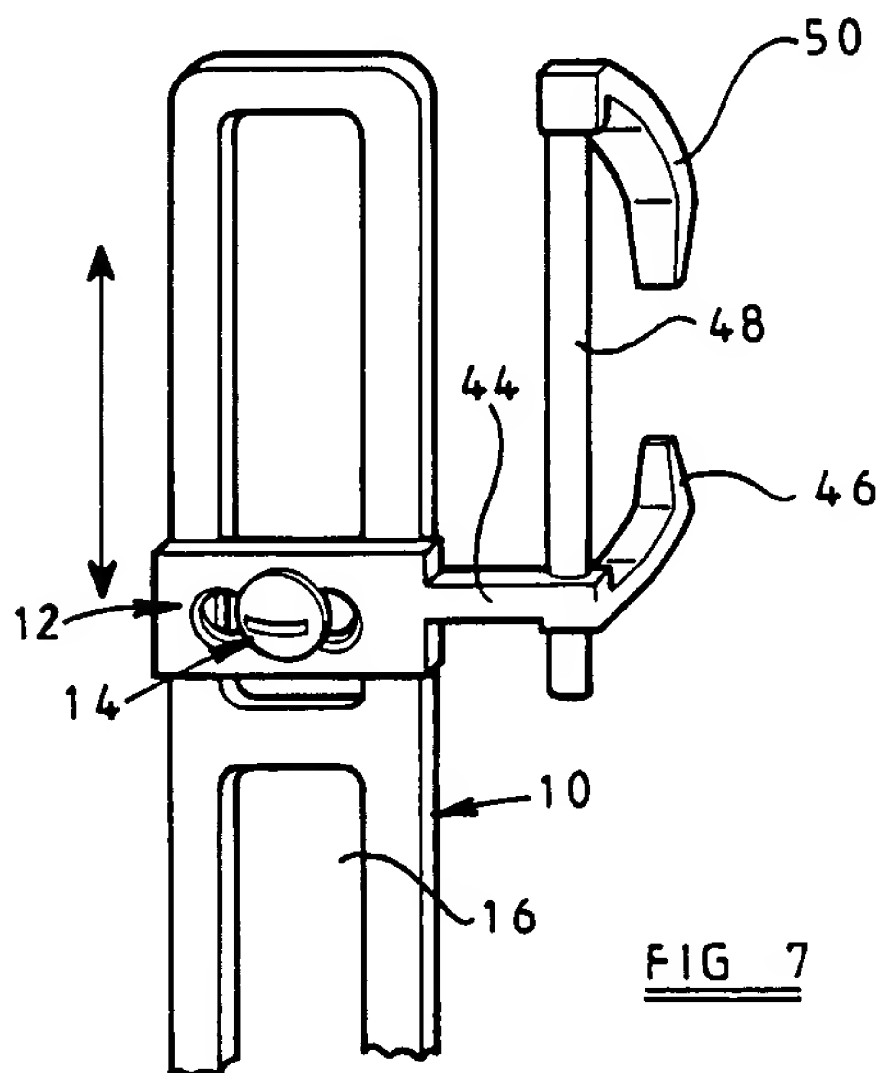
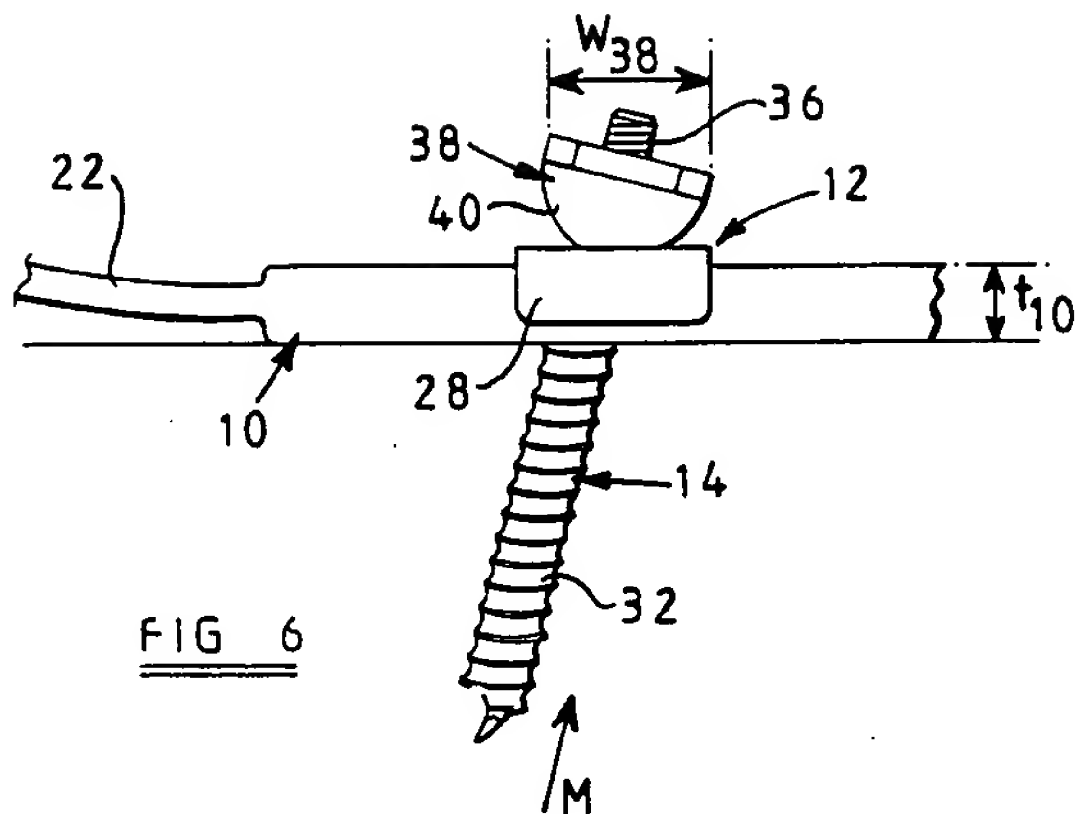
18. A system as claimed in claim 13, 14 or 15, wherein the apertured flange has a clamping member hingedly secured thereto so that a rod extending from the hooked element can be clamped between the clamping member and the flange to secure the hooked element against sliding movement.

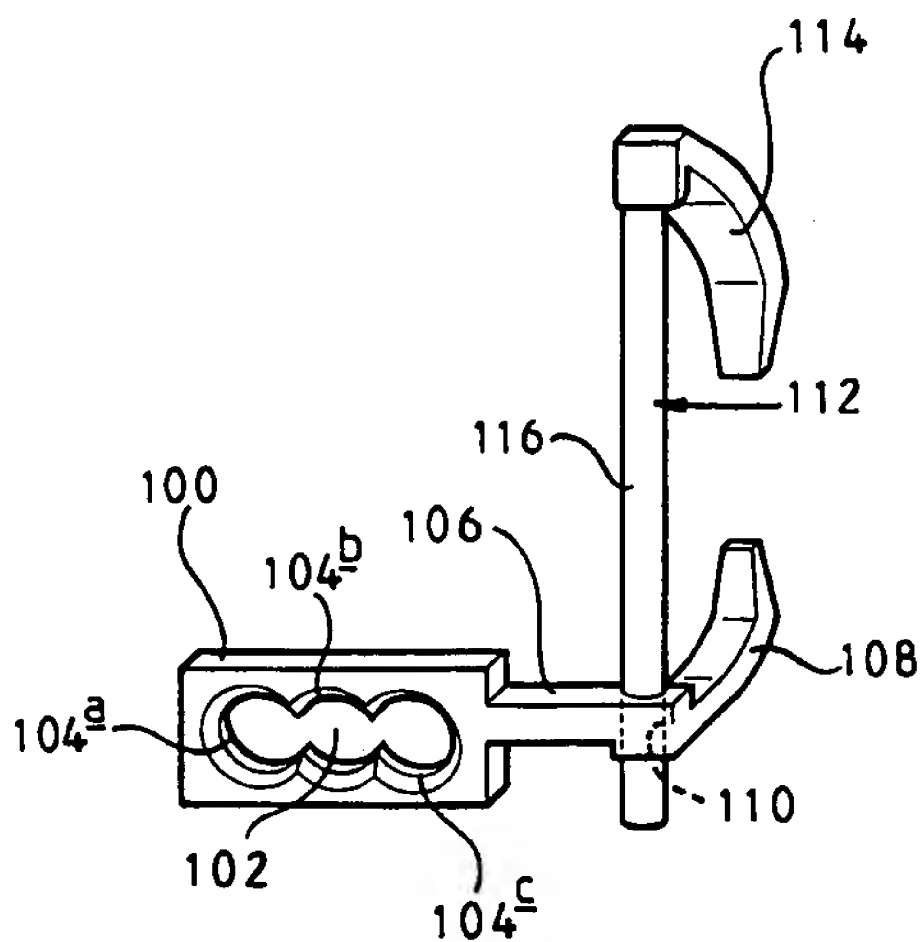
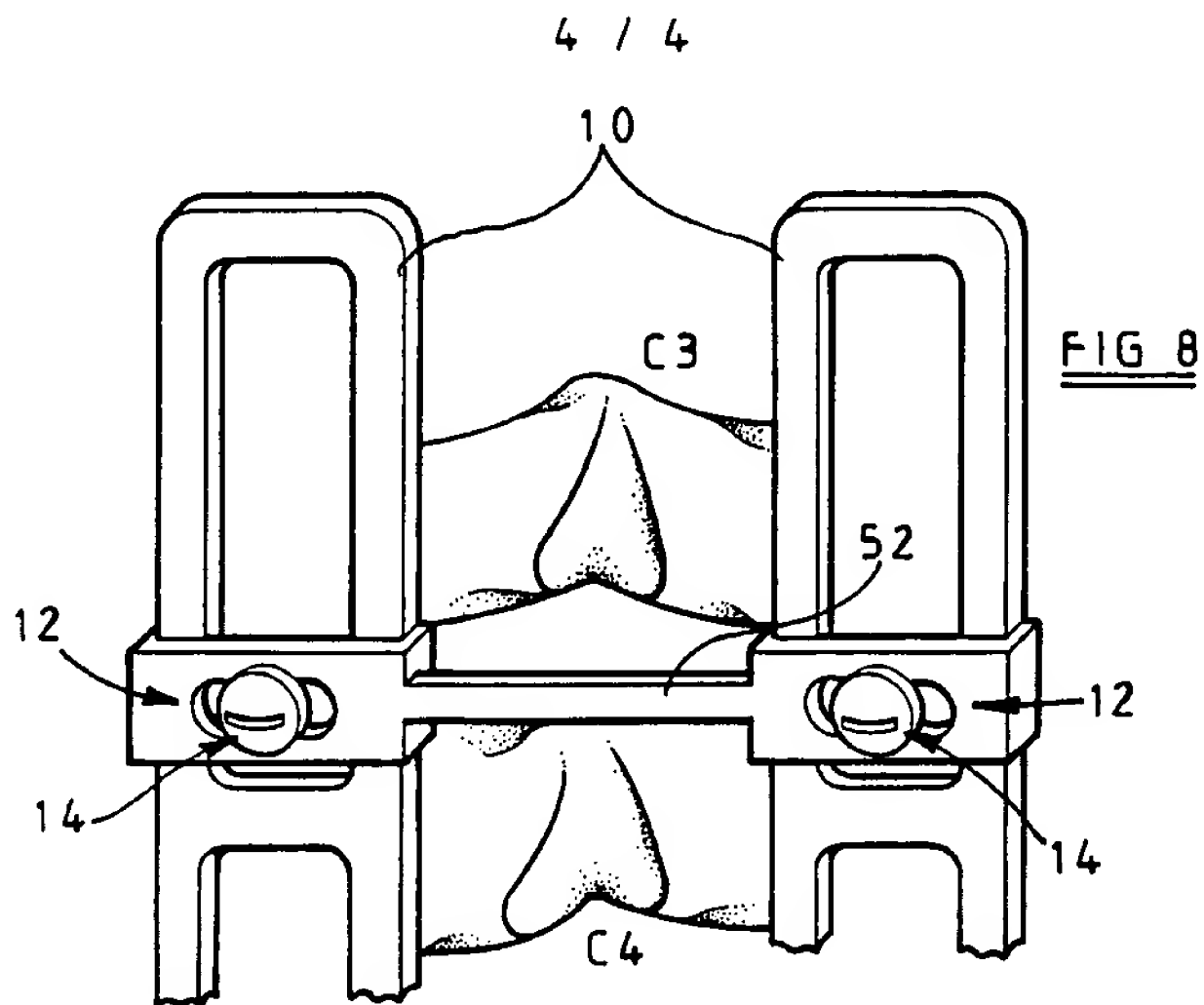
19. A system as claimed in claim 18, wherein the clamping member is apertured so that the screw or the like fixing member can pass in use through both the clamping member and the apertured flange.





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INTERNATIONAL SEARCH REPORT

Internatir Application No
PCT/Gb 97/03513

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/70

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 092 893 A (SMITH THOMAS E) 3 March 1992	1,3,8, 11,12
Y	see column 1, line 32 - line 35 see column 1, line 56 - line 60 see column 4, line 44 - line 67; figures 1,2	6,7

X	US 5 290 288 A (VIGNAUD JEAN-LOUIS ET AL) 1 March 1994	1,4,11
A	see column 2, line 4 - line 8	2
Y	see column 2, line 53 - line 58	13-17

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 March 1998

Date of mailing of the international search report

27/03/1998

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Authorized officer

Gérard, B

INTERNATIONAL SEARCH REPORT

Internatio	Application No
PCT/GB 97/03513	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 234 431 A (KELLER ARNOLD) 10 August 1993 see column 2, line 19 see column 2, line 53 - line 57 see column 4, line 4 - line 55 see figures 6,8 ---	1-3,11
Y	US 5 507 745 A (LOGROSCINO CARLO ET AL) 16 April 1996 see column 3, line 67; figures 8,12 ---	6,7
A	US 5 558 674 A (HEGGENESS MICHAEL H ET AL) 24 September 1996 see figure 2 ---	1,8,13
A	US 5 558 674 A (HEGGENESS MICHAEL H ET AL) 24 September 1996 see figure 2 ---	1,6
A	WO 95 06440 A (SOFAMOR ;ASSAKER RICHARD (BE)) 9 March 1995 see figure 16 ---	8,9,13,16
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A	WO 96 02199 A (FOURNITURES HOSPITALIERES ETS ;ONIMUS MICHEL (FR); GANGLOFF SERGE) 1 February 1996 cited in the application see figure 1 -----	18,19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 97/ 03513

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 97/03513

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